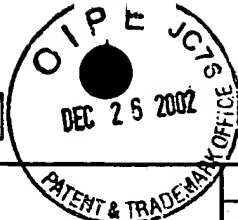


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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number	09/282,471
Filing Date	March 31, 1999
First Named Inventor	Indu Parikh
Group Art Unit	1615
Examiner Name	Susan T. Tran
Attorney Docket Number	401865/SKYE PHARMA

Sheet 1 of 10

## U.S. PATENT DOCUMENTS

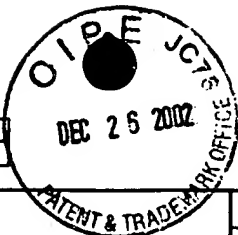
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
S.T.	A 1	2803582		Cherney	8/20/1957	
	A 2	3137631		Soloway	6/16/1964	
	A 3	3594476		Merrill	7/20/1971	
	A 4	3715432		Merrill	2/6/1973	
	A 5	3755557		Jacobs	8/28/1973	
	A 6	3937668		Zolle	2/10/1976	
	A 7	3960757		Morishita et al.	6/1/1976	
	A 8	4053585		Allison et al.	10/11/1977	
	A 9	4073943		Wretling et al.	2/14/1978	
	A 10	4078052		Papahadjopoulos	3/7/1978	
	A 11	4089801		Schneider	5/16/1978	
	A 12	4102806		Kondo et al.	7/25/1978	
	A 13	4107288		Oppenheim et al.	8/15/1978	
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	A 15	4145410		Sears	3/20/1979	
	A 16	4147767		Yapel, Jr.	4/3/1979	
	A 17	4219548		Reller	8/26/1980	
	A 18	4235871		Papahadjopoulos et al.	11/25/1980	
	A 19	4241046		Papahadjopoulos et al.	12/23/1980	
	A 20	4271196		Schmidt	6/2/1981	
	A 21	4298594		Sears et al.	11/3/1981	
	A 22	4302459		Steck et al.	11/24/1981	
	A 23	4308166		Marchetti et al.	12/29/1981	
	A 24	4309421		Ghyczy et al.	1/5/1982	
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	A 32	4340594		Mizushima et al.	7/20/1982	
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	A 34	4351831		Growdon et al.	9/28/1982	
S.T.	A 35	4356167		Kelly	10/26/1982	

Examiner Signatur	S.T.	Date Considered	1/23/03
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Application Number	09/282,471
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First Named Inventor	Indu Parikh
Group Art Unit	1615
Examiner Name	Susan T. Tran
Attorney Docket Number	401865/SKYE PHARMA

Sheet 2 of 10

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## **U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
S.T.	A 36	4369182		Ghyczy et al.	1/18/1983	
	A 37	4371516		Gregory et al.	2/1/1983	
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	A 43	4427649		Dingle et al.	1/24/1984	
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	A 45	4448765		Ash et al.	5/15/1984	
	A 46	4483847		Augart	11/20/1984	
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	A 50	4610868		Fountain et al.	9/9/1986	
	A 51	4613505		Mizushima et al.	9/23/1986	
	A 52	4622219		Haynes	11/11/1986	
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	A 57	4758598		Gregory	7/19/1988	
	A 58	4762720		Jizomoto	8/9/1988	
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	A 60	4776991		Farmer et al.	10/11/1988	
	A 61	4800079		Boyer	1/24/1989	
	A 62	4801455		List et al.	1/31/1989	
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	A 66	4826687		Nerome et al.	5/2/1989	
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S.T.	A 68	4895726		Curtet et al.	1/23/1990	

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Application Number	09/282,471
Filing Date	March 31, 1999
First Named Inventor	Indu Parikh
Group Art Unit	1615
Examiner Name	Susan T. Tran
Attorney Docket Number	401865/SKYE PHARMA

Sheet 3 of 10

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## **U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
S.T.	A 69	4961890		Boyer	10/9/1990	
	A 70	4973465		Baurain et al.	11/27/1990	
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	A 72	5100591		Leclef et al.	3/31/1992	
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	A 81	5302401		Liversidge et al.	4/12/1994	
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	A 98	5631023		Kearney et al.	5/20/1997	
	A 99	5637625		Haynes	6/10/1997	
	A 100	5645856		Lacy et al.	7/8/1997	
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	A 102	5660854		Haynes et al.	8/26/1997	
S.T.	A 103	5660858		Parikh et al.	8/26/1997	

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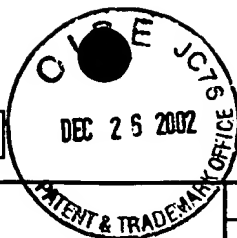
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**Complete if Known**

Application Number	09/282,471
Filing Date	March 31, 1999
First Named Inventor	Indu Parikh
Group Art Unit	1615
Examiner Name	Susan T. Tran
Attorney Docket Number	401865/SKYE PHARMA

Sheet 4 of 10

## **U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
S.T.	A 104	5662932		Amselem et al.	9/2/1997	
	A 105	5663198		Reul et al.	9/2/1997	
	A 106	5676928		Klaveness et al.	10/14/1997	
	A 107	5776491		Allen, Jr. et al.	7/7/1998	
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	A 109	5834025		de Garavilla et al.	11/10/1998	
	A 110	5851275		Amidon et al.	12/22/1998	
	A 111	5858398		Cho	1/12/1999	
	A 112	5858410		Muller et al.	1/12/1999	
	A 113	5922355		Parikh et al.	7/13/1999	
	A 114	5932243		Fricker et al.	8/3/1999	
	A 115	5972366		Haynes et al.	10/26/1999	
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S.T.	A 117	6045829		Liversidge et al.	4/4/2000	
	A 118	6267989		Liversidge et al.	7/31/2001	
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	A 120	6337092		Khan et al.	1/8/2002	
	A 121	6387409		Khan et al.	5/14/2002	
	A 122	RE32393		Wretlind et al.	4/7/1987	
	A 123	RE35338		Haynes	9/24/1996	
	A 124	3274063		Nieper et al.	9/20/1966	
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	A 126	4761288		Michael Mezei	8/2/1988	
	A 127	3216897		John C. Krantz	11/9/1965	
	A 128	3794476		E. R. Michalik et al.	2/26/1974	
	A 129	3965255		Bloch et al.	6/22/1976	
	A 130	4016100		Suzuki et al.	4/5/1977	
	A 131	4186183		Steck et al.	1/29/1980	
	A 132	4529561		Hunt et al.	7/16/1985	
	A 133	4532089		MacDonald	7/30/1985	

Examiner Signature

S.T.

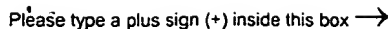
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1/25/03

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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**Complete if Known**

Application Number	09/282,471
Filing Date	March 31, 1999
First Named Inventor	Indu Parikh
Group Art Unit	1615
Examiner Name	Susan T. Tran
Attorney Docket Number	401865/SKYEPHARMA

Sheet	5	of	10
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## U.S. PATENT DOCUMENTS

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**Examiner Signature**

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Date Considered

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known

Application Number 09/282,471  
Filing Date March 31, 1999  
First Named Inventor Indu Parikh  
Group Art Unit 1615  
Examiner Name Susan T. Tran  
Attorney Docket Number 401865/SKYE PHARMA

Sheet 6 of 10

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## FOREIGN PATENT DOCUMENTS

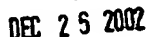
Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
ST	A 135		DE 2 513 797		Imperial Chemical Industries	10/9/1975		X
	A 136		DE 2 938 807		Green Cross Corp.	11/13/1980		X
	A 137		DE 3 421 468		Dr. Rentschler Arzneimittel Gmbtl. & Co.	12/19/1985		X
	A 138		DE 4 440 337		Rainer H. Müller	5/15/1996		X
	A 139		EP 0 193208		Technicon Instruments Corp.	9/3/1986	X	
	A 140		EP 0 052 322		Gersonde, Klaus	5/26/1982		X
	A 141		EP 0 272 091		Vestar, Inc.	6/22/1988	X	
	A 142		EP 0 330 532		Fournier Industrie et Sante	8/30/1989		X
	A 143		EP 0 418 153		Medgenix Group, S.A.	3/20/1991		X
	A 144		EP 0 456 670		B. Braun Melsungen AG	11/21/1991		X
	A 145		EP 0 456 764		B. Braun Melsungen AG	11/21/1991		X
	A 146		EP 0 499 299		Sterling Winthrop Inc.	8/19/1992	X	
	A 147		EP 0 570 829		Dr. Hans Dietl	5/12/1993		X
	A 148		EP 0 580 690		Sandoz Ltd.	2/2/1994	X	
	A 149		EP 0 605 497		Rainer Müller	3/20/1996		X
	A 150		EP 0 724 877		Laboratories Fournier	8/7/1996		X
	A 151		FR 2 617 047		Laboratories Fournier	3/20/1996		X
	A 152		GB 1 527 638		Bayer Aktiengesellschaft	10/4/1978	X	
	A 153		GB 2,046,094		Technicon Instruments Corp.	9/3/1986	X	
	A 154		HU 211 580B		FGIS	6/20/1995		X
	A 155		JP1502590		A. Nattermann & Cie	11/12/1980		X
	A 156		JP55141407		A. Nattermann & Cie	11/5/1980		X
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	A 158		JP60208910		A. Nattermann & Cie (Abstract)	11/5/1980	X	
	A 159		JP63233915		Green Cross Corp.	10/21/1985		X
	A 160		JP63502117		Liposome Technology, Inc.	9/3/1986		X
	A 161		WO 00/10531		RTP Pharma Inc.	3/2/2000	X	
	A 162		WO 00/40219		Dexcel Ltd.	7/13/2000	X	
	A 163		WO 00/41682		LG Chemical Ltd.	7/20/2000	X	
	A 164		WO 01/30372		Bask Aktiengesellschaft (Abstract)	5/3/2001	X	
	A 165		WO 8500011		University of Miami	1/3/1985	X	
	A 166		WO 8704592		Liposome Technology, Inc.	8/13/1987	X	
	A 167		WO 9104011		Riker Laboratories, Inc.	4/4/1991	X	
	A 168		WO 92/18105		Sandoz Ltd.	10/29/1992	X	
	A 169		WO 96/21439		Galephar P.R. Inc.	7/18/1996	X	
ST	A 170		WO 96/24332		Nanosystems, LLC	8/15/1996	X	

Examiner Signature	ST	Date Considered	1/29/08
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Attorney Docket Number	401865/SKYEPHARMA

Sheet	7	of	10
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Examiner Name	Susan T. Tran
Attorney Docket Number	401865/SKYE PHARMA

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## OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
ST	A 180	ROSS et al., "Aqueous Solutions of Surface-Active Solutes", <i>Colloidal Systems and Interfaces</i> , © 1988, pp. 148-151		
	A 181	SANDE et al., "Antimicrobial Agents: Antifungal and Antiviral Agents", pp. 1219-1222	1985	
	A 182	BITTMAN, ROBERT, "Sterol-Polyene Antibiotic Complexation: Probe of Membrane Structure," <i>Lipids</i> , Vol. 13, No. 10, pp. 686-691 (1978).		
	A 183	MISHRA et al., "Scientifically Speaking: Novel Injectable Formulations of Water-Insoluble Drugs", <i>Controlled Release Newsletter</i> , Vol. 17, Issue 2, (June 2000), pp. 21-30		
	A 184	BANGHAM et al., "Diffusion of Univalent Ions Across the Lamellae of Swollen Phospholipids", <i>J. Mol. Biol.</i> (1965) 13, pp. 238-252		
	A 185	HUANG et al., "Interaction of the N-terminus of Sterol Carrier Protein 2 with Membranes: Role of Membrane Curvature", <i>Biochem. J.</i> (1999) Vol. 8, pp. 593-603		
	A 186	GREGORIADIS, GREGORY, "The Carrier Potential of Liposomes in Biology and Medicine", <i>New Engl. J. Med.</i> , (1976) Vol. 295, No. 13, pp. 704-710		
	A 187	CUDD et al., "Liposomes Injected Intravenously into Mice Associate with Liver Mitochondria", <i>Biochem. Biophys. Acta</i> , (1984) Vol. 774, pp. 169-180		
	A 188	BENZ et al., "Electrical Capacity of Black Lipid Films and of Lipid Bilayers Made from Monolayers", <i>Biochem. Biophys. Acta</i> , (1975) Vol. 394, pp. 323-334		
	A 189	GOODMAN and GILLMAN'S, "The Pharmacological Basis of Therapeutics," 7 <sup>th</sup> Ed., <i>MacMillan Publishing Co.</i> , New York (1985) Chap. 15, p. 312		
	A 190	CHERNEY, L.S., "Tetracaine Hydroiodide: A Long Lasting Local Anesthetic Agent for the Relief of Postoperative Pain", <i>Anesth. Analg.</i> (1963) Vol. 42, No. 4, pp. 477-481		
	A 191	HAYNES et al., "Metal-Ligand Interactions in Organic Chemistry and Biochemistry", <i>B. Pullman and N. Goldblum (eds.)</i> , part 2, (1977), pp. 189-212		
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	A 193	HAYNES et al., "Ultra-Long Duration Local Anesthesia Produced by Intra-Dermal Injection of Lecithin-Coated Methoxyflurane Microdroplets", <i>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</i> , (1987) Vol. 14, pp.293-294		
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ST	A 195	GENNARO et al., "Sustained-Release Drug Therapy," <i>Remington's Pharmaceutical Sciences</i> , 17 <sup>th</sup> Ed., (1985), p. 1645		
	A 196	<del>"Derived Diameters and Distribution Statistics," from an unknown web site, 6 pages</del>		
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Examiner Signature	ST	Date Considered	01/24/03
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Substitute for form 1449A/B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

## Complete if Known

Application Number	09/282,471
Filing Date	March 31, 1999
First Named Inventor	Indu Parikh
Group Art Unit	1615
Examiner Name	Susan T. Tran
Attorney Docket Number	401865/SKYE PHARMA

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## OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
S.T.	A 198	CHULIA et al., Powder Technology and Pharmaceutical Processes, (1994), pp. 66-67.		
	A 199	HERBERT A. LEIBERMAN and LEON LACHMAN, Eds., <i>Pharmaceutical Dosage Forms, Tablets</i> , Vol. 1, (1980), p. 13		
	A 200	MIYAJIMA, KOICHIRO, "Role of Saccharides for the Freeze-Thawing and Freeze-Drying of Liposome", <i>Advanced Drug Delivery Review</i> , Vol. 24, (1997), pp. 151-159		
	A 201	BUCHMULLER et al., "Cryopel: Ein neues Verfahren zum Pelletieren und Frosten Biologischer Substrate," <i>Gas Aktuell</i> , 35, 1(1989), pp. 10-13		X
	A 202	WU et al., "Pharmacokinetics of Methoxyflurane After Its Intra-Dermal Injection as Lecithin-Coated Microdroplets," <i>Journal of Controlled Release</i> , (1989), Vol. 9, pp. 1-12		
	A 203	PACE et al., "Novel Injectable Formulations of Insoluble Drugs", <i>Pharmaceutical Technology</i> , Vol. 23, No. 3, (March 1999), pp. 116-134		
	A 204	ROMPP'S CHEMIE LEXIKON, 2 Aufl., Bd. 1, (1950), Stichwort, "Emulsion"		
	A 205	BERGMANN, LUDWIG, <i>Der Ultraschall</i> , 5 Aufl., (1949), Stuttgart, S. 551-564, 672f		
	A 206	LEHNINGER BIOCHEMISTRY, "The Molecular Basis of Cell Structure and Function", (1970) Chapter 10		
	A 207	GUZMAN et al., 1088 J. Pharm. Sci 82 (1993) No. 5 pp. 498-502 Formation and Characterization of Cyclosporine-Loaded Nanoparticles.		
	A 208	NAPPER, "Polymeric Stabilizations of Colloidal Dispersions", (1983).		
	A 209	MULLER et al., Emulsions and Nanosuspension, Chap. 9 (1998) p. 163		
	A 210	LOURENCO et al., Int. J. of Pharm. 138 (1996), 1-12, "Steric stabilization of nanoparticles: size and surface properties".		
	A 211	LUCKHAM Pestic. Sci., 1989, 25, 25-34, "The Physical Stability of Suspension Concentrates with Particular etc."		
	A 212	CALVOR et al. Pharm. Dev. Tech., 3(3), 297-205, 1998, "Production of Microparticles by High Pressure etc."		
S.T.	A 213	[LSP4]La Fuma Polymery 1998 43 nr 2, 104-108, "The role of water-soluble polymers at the solid/liquid etc."		
	A 214	Website <a href="http://userpage.fu-berlin.de/~kayser/nanosuspensionen.htm">http://userpage.fu-berlin.de/~kayser/nanosuspensionen.htm</a>		
S.T.	A 215	SIEKMANN et al. Pharm. Pharmacol Lett (1994) 3:225-228 "Melt-homogenized Solid Lipid Nanoparticles Stabilized by the Non-ionic Surfactant Tyloxapol".		
S.T.	A 216	MULLER et al., "Nanosuspensions for the I.V. Administration of Poorly Soluble Drugs-Stability During Sterilization and Long-Term Storage", Dept. of Pharmaceutics, Biopharmaceutics and Biotechnology, The Free University of Berlin, Kelchstraße 31, D-12169 Berlin, Germany (1995)		

Examiner Signature	S.T.	Date Considered	1/24/03
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\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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